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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/213,968 12/17/98 BEALE

P 1207-003D

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EXAMINER

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ART UNIT

PAPER NUMBER

1653

2

DATE MAILED:

03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/213968

Applicant(s)

P. Beale et al

Examiner

J. Russel

Group Art Unit

1653

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 12-17-1998
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 9, 10, 13, 15 and 17-21 is/are allowed.
- ☒ Claim(s) 1-8, 11, 12, 16, and 22-26 is/are rejected.
- ☒ Claim(s) 14 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the declaration incorrectly states that the inventors are sole inventors. When there is more than one inventor, they are properly joint inventors.

2. The disclosure is objected to because of the following informalities: While there is an Example III at page 20 of the specification and an Example V at page 28 of the specification, there does not appear to be an Example IV. The examples should be numbered consecutively. Appropriate correction is required.

3. Claims 2, 3, 23, and 26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the word "can" to define the weight ratios in claims 2 and 3 is indefinite because it is not clear if the weight ratios are required or not. It is suggested that "can range" be changed to "ranges" at each occurrence. The result of claim 22 is that the Target of said protein composition is attained (see step (j)). However, the preamble to the claim recites that a desired amino acid profile is to be attained, and the claim is unclear as to what the relationship is between the desired amino acid profile and the Target. The purpose of claim 22, step (d) is not clear, because there is no subsequent use in the claimed method of the identified amino acids in the source of amino nitrogen that exceed the maximum allowable levels in the

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Target. There is no antecedent basis in the claim for the phrase “the maximum allowable levels” at claim 22, line 7. Note that step (a) of the claim only recites setting a target amino acid profile, and does not recite also setting a maximum allowable level of amino acids. Claim 23, step (e), is unclear because it states that an amount is to be calculated, but the aK value calculated in the step are dimensionless ratios, not amounts. Claim 23, step (e), is unclear because it is not clear how or by what criteria the amino acid of the source of amino nitrogen is to be selected. To the extent that aK values are calculated for all amino acids, which is implied by steps (e) and (f), it is not clear what purpose is served by designating the first amino acid as a “selected” amino acid or by dividing the aK calculations into two separate method steps. Claim 23, step (e), is unclear because it states that grams of selected amino acid are to be used to calculate the aK values, but there is no previous mention in the claim of any basis for calculating grams of amino acids. The claim does not set forth any relationship between the amino acid profiles of steps (a) and (c) and the grams of selected amino acid of step (e). Claim 23, step (e), is unclear because it states that the aK values will be less than 1.0. However, the aK values will not necessarily be less than 1.0 for all of the amino acids, e.g., for those amino acids identified in step (d), and the aK values could be greater than 1.0 for all of the amino acids, e.g. if the basis upon which the amino acid profile for the source of amino nitrogen is calculated is much larger than the basis upon which the amino acid profile for the Target is calculated. At claim 26, line 3, the recitation of “exercise” in the Markush group is at best redundant to the generic terminology “strenuous exercise” at line 2. To the extent that the exercise at line 3 is not required to be strenuous, however, it contradicts the

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generic terminology at line 2.

4. Claims 7, 11, and 14 are objected to because of the following informalities: At claim 7, line 4, and claim 14, line 4, Applicants are requested to check the spelling of "pyruvamides" (compare page 13, line 5, of the specification). At claim 11, line 2, "from" should be changed to "form", and "a" should be inserted after "of". Appropriate correction is required.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11, 12, 16, and 23-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 5,716,926. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '926 patent anticipate instant claims 1-8, 11, 12, 16, and 23-25. Note that Applicants' specification at page 11, lines 2-3, indicates that the claimed proline amounts embrace the sum of proline and hydroxyproline in the composition. With respect to instant claims 6, 8, 11, 12, 16, and 23-25, because the same anabolic protein composition is being administered to the same mammal in the claimed methods of the '926 patent, inherently fat loss

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will be increased and percent body fat will be decreased to the same extent claimed by Applicants. Note also that the '926 patent's claimed goals of increasing the protein concentration, lean body mass, and muscle mass in a mammal are consistent with Applicants' claimed goals of increasing fat loss and decreasing percent body fat. With respect to instant claim 26, it would have been obvious to one of ordinary skill in the art in the claimed method of the '926 patent to administer the claimed anabolic protein compositions to mammals engaged in strenuous exercise, including anaerobic exercise, because such mammals commonly use anabolic protein compositions and commonly desire to enhance their physical endurance and to increase their protein concentration, lean body mass, and muscle mass as claimed in the '926 patent.

6. The effective filing date of instant claims 1-26 is deemed to be December 17, 1998, the filing date of the instant application. The instant claims are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 08/951,547 because the parent application, under the test of 35 U.S.C. 112, first paragraph, does not disclose compositions comprising 6.0 to 15 gms of proline per 100 gms of protein (the parent application is limited to compositions comprising 6.0 to 8.2 grams of proline and 3.5 to 6.5 grams of hydroxyproline), does not disclose increasing or inducing fat loss or decreasing percent body fat or increasing the muscle mass of a mammal by administering only an anabolic protein composition not comprising any pyruvate, does not disclose pyruvyl-creatine or pyruvyl-glutamine, does not disclose anabolic protein compositions comprising about 60-65% by weight albumin protein and not comprising any pyruvate, does not disclose anabolic protein compositions comprising about 15-30% by

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weight albumin protein and about 60-70% by weight whey protein and not comprising any pyruvate, does not disclose anabolic protein compositions comprising about 56-60% by weight whey protein concentrate and about 9.5-13.5% by weight albumin protein and not comprising any pyruvate, does not disclose the method of instant claim 22, and does not disclose administering an anabolic protein composition to a mammal engaging in anaerobic exercise.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

The following is a quotation from 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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(c) Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

8. Claims 1-8, 11, 12, 16, and 23-26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,716,926. See the above obviousness-type double patenting rejection. In addition, column 4, lines 20-26, teaches the benefits of administering the disclosed and claimed compositions to mammals undergoing strenuous exercise.

The applied reference has a common inventor with the instant application. Based upon the

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earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 17 USPQ2d 1885 (Fed. Cir. 1991).

9. Claims 1-8, 11, 12, 16, and 23-25 are rejected under 35 U.S.C. 102(f) and/or (g) as being anticipated by U.S. Patent No. 5,716,926, and claim 26 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,716,926. See the above obviousness-type double patenting rejection. Note that the instant application and U.S. Patent No. 5,716,926 are not currently commonly assigned.

Even if an assignment is filed in the instant application so that the instant application and U.S. Patent No. 5,716,926 become commonly assigned, claims 1-8, 11, 12, 16, and 23-25 will be directed to an invention not patentably distinct from claims 1-28 of U.S. Patent No. 5,716,926, and the commonly assigned U.S. Patent No. 5,716,926, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee would be required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show

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that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement would result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

10. Claims 6, 11, 12, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fregly et al. Fregly et al teach a composition comprising pyruvate and alanine. The composition can be dehydrated in the form of a powder which can be reconstituted with water and used to ameliorate the effects of physical exertion, e.g., of strenuous exercise. The composition promotes the metabolism of carbohydrates as opposed to fat or protein, and thus prevents depletion of amino acids and prevents a reduction in the body's ability to repair muscle. The composition enhances physical endurance. See, e.g., column 1, lines 18-20; column 5, lines 7-20; column 6, line 52 - column 7, line 38; column 8, lines 29-42; column 9, lines 32-38; and the claims. The alanine corresponds to Applicants' anabolic protein composition. Because the same composition is being administered to the same mammal by the same method steps, inherently the method of Fregly et al will result in an increase in fat loss, a decrease in percent body fat, and an increase in the muscle mass of a mammal to the same extent claimed by Applicants.

11. Claims 6, 11, 12, 23, 24, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Brantman. Brantman teaches a composition comprising a combination of amino acids. The

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amino acids are in crystalline form and dissolved in water and used to stimulate and maximize muscle protein synthesis in athletes undergoing strenuous exercise. See, e.g., column 3, lines 18-22 and 27-30; column 4, lines 25-30 and 53-61; column 5, lines 25-38; and the claims. The combination of amino acids corresponds to Applicants' anabolic protein composition. Because the same composition is being administered to the same mammal by the same method steps, inherently the method of Brantman will result in an increase in fat loss and a decrease in percent body fat to the same extent claimed by Applicants.

12. Claims 6, 11, 12, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. Clark et al teach administering IGF-I to increase the body weight and to increase the lean mass to fat ratio in a mammal. The IGF-I can be stored in lyophilized form and then reconstituted with water. IGF-I is an anabolic protein. See, e.g., column 1, lines 24-25; column 10, lines 29-48; column 11, lines 37-42; column 14, lines 37-45; and column 15, lines 47-49. Because the same composition is being administered to the same mammal by the same method steps, inherently the method of Clark will result in an increase in fat loss and an increase in muscle mass to the same extent claimed by Applicants.

13. Claims 9, 10, 13, 15, and 17-21 are allowed. Claim 14 would be allowable if rewritten or amended to overcome the claim objection(s) set forth in this Office action. While the individual ingredients are known in the art as nutritional agents, the prior art of record does not teach or suggest the specific combinations of ingredients in the specific concentrations recited in instant claims 9, 10, and 17.

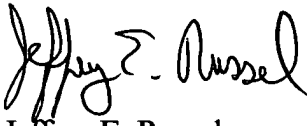
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Miller et al is cited as art of interest, teaching the use of whey protein to promote skeletal muscle protein synthesis and to decrease body fat. However, Miller et al do not teach or suggest whey protein in combination with albumin or free amino acids in the proportions recited in Applicants' claims 10 and 17.

Beale '469, Beale '767, and Beale '252 are cited as art of interest, but do not teach or suggest the instant claims invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 305-7401 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

March 17, 2000